Patient Safety Specialist

Job ID
REQ-10056826
Jul 01, 2025
Taiwan

Summary

To support management of Patient Safety operational processes at Country Organization ensuring compliance with Novartis global and local procedures, national and international regulations/ standards/ guide-lines for vigilance of both marketed and investigational products from Novartis Group.
To mentor less experienced Patient Safety associates through Patient Safety processes, systems, and operations. To support the implementation of local projects/ initiatives under close collaboration with the CPSH and/or PSGM or PGR.

About the Role

Major accountabilities:

1. Manage the collection, processing, documentation, reporting and follow-up of all adverse event reports for all Novartis products from Clinical Trials, Non-interventional Studies, Patient Oriented Program (POPs), Literature, Spontaneous Reports, and any other source of information.

2. Transcribe, translate, and enter data from source documents into safety systems accurately and consistently with focus quality and on timeliness. When case processing activities are externalized, liaise with the respective External Service Providers to ensure Novartis Procedures' compliance.

3. Manage reporting/submission/distribution of safety reports/updates/information (e.g., SAE, SR, IN/SUSAR, PSUR, SUSAR Listing) to TFDA and/or clinical operations in cooperation with other Country Organization Departments.

4. Develop, update, and implement local procedures to ensure compliance with Patient Safety global procedures and national requirements.

5. Interact and collaborate with other departments (such as Medical Affairs, Marketing, SSO, etc.) to ensure that any projects/ initiatives that potentially involve safety data collection (POPs, DEAs, SM/SML, etc.) follow the Novartis vigilance requirements.

6. Management and distribution of vigilance clauses to other departments (such as Legal, Procurement, etc.) to be included in local agreements if necessary

7. Advice the owners of local contracts/ agreements with impact in the vigilance system, about the vigilance provisions to be included, as required per Novartis procedures and/or applicable regulations.

8. Ensure compliance with the commitments disposed in the contracts/ agreements. Ensure the applicable local contracts/ agreements are tracked in the respective Pharmacovigilance Agreement SharePoint. Ensure any significant departure from the standard vigilance templates are communicated and endorsed by the global

PS Alliance group.

9. Perform reconciliation with other departments (e.g., Medical Information, Quality Assurance, and Third-party contractors, as applicable) for potential AEs resulting from medical inquiries, quality related complaints and other sources.

10. Management and maintenance of all relevant local Patient Safety databases

11. Ensure that relevant local literature articles are screened as appropriate.

12. Prepare and submit KPI reports on compliance in a timely manner including identification of root cause(s) for late reporting to TFDA, development and implementation of corrective action(s) as needed.

13. Develop and update training materials for vigilance and ensure training of Country Organization associates on relevant Patient Safety procedures for AE reporting, including field force and third-party contractors, as applicable.

14. Ensure support to the internal audits, TFDA inspections and implementation of the respective CAPA plan. Support the onboarding of new PS associates and mentor less experienced Patient Safety associates under close collaboration with the CPSH or PSGM or PGR.

15. Other agreed tasks assigned by manager

Key performance indicators:

- Quality and timely reporting of KPI and safety reports/updates
- No critical findings in audits or inspections
- Successful onboarding/ mentoring of assigned PS associates (if applicable) and/or successful project management (as applicable)
- Internal and external customer satisfaction

Minimum Requirements:

Education:

Health Care Sciences Professional (e.g., Medical Doctor, Nurse, Pharmacist), life science degree.

Pharmacist is a plus

Work Experience:

- At least 1 year experience in Pharmacovigilance or drug safety within the pharmaceutical industry
- Proven expertise in case processing, project management
- Strong knowledge of PV regulations and guidelines(eg. ICH, GPvP)
- Experience in risk management plans ,and PSUR/PBRER is a plus
- Experience in health authority inspections or internal audit related to PV activities is a plus

Skills:

- Familiarity with Safety databases(e.g. Argus, ARISg) and electronic reporting systems.
- Excellent communication skills for collaboration with internal stakeholders and external supplier partners
- Quality and results oriented
- Project management skills

- Attention to detail, with a high level of accuracy in documentation and safety data review
- Strong excel and data handling skills is a plus
- Experience applying AI or machine learning tools in pharmacovigilance workflows (e.g., automation, Microsoft Automate) is a plus

Languages :

- Fluent in both written and spoken English
- Fluent in both written and spoken Chinese

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Development
Business Unit
Innovative Medicines
Location
Taiwan
Site
Taipei
Company / Legal Entity
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Functional Area
Research & Development
Job Type
Full time
Employment Type
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Shift Work
No
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